

Attorney Docket No.: 6196.210-US  
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**IN THE CLAIMS:**

1-12 (Cancelled)

13. (Currently Amended) A drug delivery device comprising:

a piston rod having at least one threaded portion (4);

a dose dial sleeve (17) threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;

a drive sleeve (20) for driving the piston rod; and

a clutch (21), which is comprised of one or more components (33, 32), that releasably couples the dose dial sleeve (17) and the drive sleeve (20); and

wherein:

(i) during the dose setting operation the dose dial sleeve (17) and the drive sleeve (20) are coupled by the clutch so that they rotate together; and

(ii) during injecting of medication from the device, the dose dial sleeve (17) is decoupled from the drive sleeve (20) and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve (20) does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

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14. (Previously Presented) The device of claim 13, wherein the drive sleeve is coupled to a gear box that is in turn coupled to the threaded piston rod so that portion of the longitudinal force exerted by the user that is transmitted to the piston rod is transmitted thru both the drive sleeve and the gear box and wherein the gear box multiplies the force.

15. (Previously Presented) The device of claim 13, wherein a longitudinal force exerted by a user in a direction toward the injecting end of the device is transmitted thru the drive sleeve to the piston rod; and

wherein the longitudinal force also acts upon the dose dial sleeve and, as a result of this longitudinal force and longitudinal movement of the drive sleeve, the dose dial sleeve rotates during injecting of medication from the device even though the dose dial sleeve is rotationally decoupled from the drive sleeve during injecting.

16. (New) A drive mechanism for use in a drug delivery device comprising a housing (1) having a helical thread (6), a dose dial sleeve (17) having a helical thread engaged with the helical thread of the housing, a drive sleeve (20) releasable connected to the dose dial sleeve (17), and a clutch (21) located between the dose dial sleeve (17) and the drive sleeve (20), wherein,

a) when the dose dial sleeve (17) and the drive sleeve (20) are coupled, both are allowed to rotate with respect to the housing (1), and

b) when the dose dial sleeve (17) and the drive sleeve (20) are de-coupled, rotation of the dose dial sleeve (17) with respect to the housing (1) is allowed, while rotation of the drive sleeve (20) with respect to the housing (1) is not allowed,

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whereby axial movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction toward a drug expelling end of the drug delivery device.

17. (New) A drive mechanism according to claim 16, wherein a piston rod (4) is provided which is adapted to operate through the housing (1) and transfer the force in the longitudinal direction toward the drug expelling end of the drug delivery device and wherein the dose dial sleeve and drive sleeve are decoupled during dose administration but are coupled during dose setting.

18. (New) A drive mechanism according to claim 17, wherein the piston rod (4) is provided with a thread which is engaged by a nut (13) which is screwed along the threaded piston rod (4) away from a defined position in the housing (1) to set a dose and is pressed back to the defined position carrying the piston rod (4) with it to inject the set dose.

19. (New) A drive mechanism according to claim 18, wherein a gearbox (9) having gear wheels and racks in permanent engagement is provided between the drive sleeve (2) and the nut (13) through which gearbox (9) rotation of the drive sleeve (20) is transmitted directly to the nut (13) causing the nut (13) to rotate and axial movement of the drive sleeve (20) relative to the housing (1) is transmitted to the nut (13) causing the nut (13) to move axially.

20. (New) A drive mechanism as in claim 17, further comprising a means for preventing a dose from being set that is larger than the amount remaining in a drug delivery device containing the drive mechanism.

21. (New) A drive mechanism as in claim 17, further comprising a dose limiter that prevents a dose from being set that is larger than the amount remaining in a drug delivery device containing the drive mechanism.

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22. (New) A drug delivery device and drive mechanism comprising:  
a housing (1);  
a dose dial sleeve (17) threadedly engaged with a threaded portion of the device, the threaded portion being located between a first end of the device and a second end of the device,  
a drive sleeve (20),  
and a clutch releasably coupling the dose dial sleeve and the drive sleeve (20),  
wherein,

when the dose dial sleeve (17) and the drive sleeve (20) are coupled during dose setting, both are allowed to rotate with respect to the housing (1), and

when the dose dial sleeve (17) and the drive sleeve (20) are decoupled during dose administration, rotation of the dose dial sleeve (17) with respect to the housing (1) is allowed, while rotation of the drive sleeve (20) with respect to the housing (1) is not allowed, whereby axial movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction to the proximal end of the drug delivery device.

23. (New) The apparatus of claim 22, wherein the threaded portion is fixed to the housing so that it cannot rotate with respect to the housing.

24. (New) The apparatus of claim 23, wherein the threaded portion is integral with the housing and wherein the drive further comprises a piston rod having at least a threaded section and wherein the piston rod reacts to a force on the drive sleeve and moves axially to expel drug from the device.

25. (New) The apparatus of claim 23, wherein the device further comprises a piston rod having comprising a first portion that is a threaded portion and wherein the piston rod receives a force that is transmitted from one end of the device thru the drive sleeve and as a result of the force the piston rod moves axially to expel drug from the device thru a needle.

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26. (New) The apparatus of claim 13, wherein a gear box directly drives the piston rod and wherein the gear box is driven by the drive sleeve, which receives a force from a user pressing on an injection button component that is coupled to or integral with the drive sleeve, thereby making the drive sleeve an indirect but necessary driver of the piston rod.
27. (New) The apparatus of claim 13, wherein the piston rod has the same pitch has pitch of the dose dial sleeve.
28. (New) The apparatus of claim 13, wherein the piston rod has a different thread configuration from that of the dose dial sleeve.
29. (New) The apparatus of claim 13, wherein the pitch of the dose dial sleeve differs from that of the piston rod.
30. (New) A drug delivery device comprising a dose dial sleeve, a drive sleeve, a housing, and a clutch that couples and uncouples the drive sleeve from the dose dial sleeve and wherein when the drive sleeve and dose dial sleeve are coupled during dose setting both rotate together with respect to the housing and when they are uncoupled during drug delivery the drive sleeve does not rotate with respect to the housing but the dose dial sleeve does.
31. (New) The device of claim 30, wherein the dose dial sleeve rotates during drug administration to a zero position upon completion of drug delivery.
32. (New) The device of claim 30 or 31 further comprising a rod that moves axially to expel drug from the device, the rod comprising a first threaded portion and a second portion and wherein the dose dial sleeve is threadedly engaged with a housing.
33. (New) The device of claim 32, wherein the first threaded portion extends in the direction toward a drug expelling end of the device.
34. (New) The device of claim 33, wherein the second portion engages drive components.
35. (New) The device of claim 33, wherein the piston rod has at least two different cross-sectional shapes as it is traversed from a proximal end to a distal end.
36. (New) A drug delivery device and drive mechanism comprising:

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a housing;  
a dose dial sleeve threadedly engaged with a portion of the device, the portion being located in between a needle end of the device on which a needle is mountable and an opposite end of the device,  
a drive sleeve,  
and wherein the dose dial sleeve and the drive sleeve are releaseably coupled together so that:

during dosing setting, the dose dial sleeve and the drive sleeve are coupled and both the dose dial sleeve and the drive sleeve rotate together with respect to the housing, and

during dose administration: the dose dial sleeve and the drive sleeve are de-coupled and the dose dial sleeve rotates with respect to the housing and the drive sleeve moves axially toward the distal end without rotating with respect to the housing.

37 (New) The device of claim 36, further comprising a piston rod that moves in a direction toward the needle end during dose administration and wherein the piston rod has two different shapes as it is traversed along its length and wherein a clutch is functionally disposed between the dose dial and the drive sleeve to allow for the coupling and uncoupling of the dose dial from the drive sleeve.

38. (New) The device of claim 37, wherein the device further comprises a dose limiter that prevents a dose from being set that is larger than the contents remaining in the device and wherein the drive sleeve is operably coupled to a piston rod and wherein motion of the drive sleeve toward the needle end results in the piston rod moving toward the needle end.

39. (New) The device of claim 37, wherein during dose administration the drive sleeve moves a distance that is greater than the distance the rod moves.

40. (New). A medication delivery device for expelling settable doses of medication, the device comprising: an injection end, a housing, a dose setting drum comprising a

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scale indicating various dose sizes, and a tubular element that is reversibly rotationally coupled to the dose setting drum so that during dose setting the tubular element and the drum rotate together but during dose administration the tubular element is rotationally decoupled from the drum so that the drum rotates back to a zero position while the tubular element moves longitudinally toward the injection end,

the device further comprising a rod that comprises a first threaded portion that extends thru a portion of the housing, the piston rod coupled to the tubular element so that when the tubular element moves toward the injection end of the device, the rod also moves toward the injection end but wherein the rod travels a different distance than the tubular element,

and wherein the tubular element and drum move away from the injection end during dose setting and move axially toward the injection end when a force is applied to either one or applied to both during dose administration.

41. (New) The device of claim 40, wherein the distance the rod travels is less than the distance the tubular element travels.

42. (New) The device of claims 40 or 41, wherein it further comprises a dose setting limiter that prevents a dose that is larger than that remaining in the device from being set and wherein the tubular element is positively precluded from rotating during dose administration.

43. (New) The device of claims 40 or 41, wherein it further comprises a dose setting limiting means for preventing a dose that is larger than that remaining in the device from being set.

44. The device of claims 42, wherein the drum is threadedly engaged with the housing

45. The device of claims 44, wherein the housing has an internal thread.

46. The device of claim 42, wherein the housing has an internal thread and the drum is threadedly engaged with the internal housing thread.

47. (New) A drug delivery device comprising:

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a piston rod (4);

a dose dial sleeve (17) threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;

a drive sleeve (20) for driving the piston rod; and

a clutch that releasably couples the dose dial sleeve (17) and the drive sleeve (20); and wherein:

(i) during the dose setting operation the dose dial sleeve (17) and the drive sleeve (20) are coupled by the clutch so that they rotate together; and

(ii) during injecting of medication from the device, the dose dial sleeve (17) is decoupled from the drive sleeve (20) and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve (20) does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

48. (New) The device of claim 47, wherein the drive sleeve is operably coupled to the piston rod and transmits a force to the piston rod.

49. The device of claim 48, wherein the piston rod comprises a threaded portion.

50. (New) A drug delivery device comprising:

a piston rod;

a dose dial threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose



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setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale; a drive sleeve for transmitting a force that is received at one end of the device to drive the piston rod; and wherein the dose dial and the drive sleeve are releasably coupled so that when the device is in a dose setting mode, the dose dial and drive sleeve rotate together and allow a predetermined dose to be set, but when the device is injecting the predetermined dose the dose dial and the drive sleeve are decoupled and the dose dial rotates with respect to the drive sleeve and rotates to a zero position upon completion of the injection and the drive sleeve moves axially toward an injecting end of the device and wherein the drive sleeve moves a distance that is greater than a distance that is moved by the piston rod during the injecting of the predetermined dose.

51. (New) The device of claim 50, wherein the piston rod comprises a first section that is threaded.

52. (New) The device of claim 51, wherein a middle portion (112) of the piston rod is unthreaded.

53. (New) The device of claim 52, wherein the device is a medication injection pen.